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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,698	12/19/2003	Sign Erickson Varner	56086 (71699)	3885

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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
05/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/740,698	VARNER ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-127 and 129-137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-127 and 129-137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The phrase "that is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a)" should not be used in the declaration and should be replaced with "which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56".

Drawings

2. The drawings were received on February 19 2008. These drawings are acceptable.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the cap element being sized to provide a cross-section larger than the cross-section area of the coil or the zig-zag shape or the cross-section of the coil-shaped member. The specification fails to

disclose the cap element being sized to prevent the cap element from passing through an incision where the cap element mates against the patient eye outer surface. The specification also fails to disclose the body member being in contact with intravitreal fluid. As to Applicant's arguments in lines 8-24 of page 17 of the Remarks filed February 19 2008, there is no disclosure of the cap element mating against the outer surface of the patient eye in the paragraphs cited by the Applicant or elsewhere in the specification. There is disclosure of the cap element abutting against the outer surface of the patient eye. There is also no disclosure of the body member being in contact with intravitreal fluid. There is only disclosure of a large intravitreal surface area.

Claim Objections

4. Claims 108 and 130 are objected to because of the following informalities: Claim 108 recites the limitation "the cap" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 130 is objected to as this multiple dependent claim does not provide proper antecedent basis for the coil shape or the zig-zag shape when dependent from claims 79, 111, and 129. Similarly, claim 130 does not provide proper antecedent basis for the coil-shaped member when dependent from claims 68 and 116. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 130 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The cap being sized to provide a cross-section about twice as large as the cross-section of the coil shape, zig-zag shape, or the coil-shaped body member is not disclosed in the specification as originally filed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 108 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 108, it is unclear if a cap is being claimed or if the cap in claim 108 refers to the cap element recited in claim 99.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 83-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman et al (U.S. Patent No. 6,478,776). Rosenman et al disclose a method of treating a patient comprising delivering a delivery device comprising a helical, substantially Z-shaped, body member (12) having at least five deviations from a linear path and that has a shape and a cap element (56) at a proximal end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The body member (12) has a coil shape or zig-zag shape as seen in Figures 18 and 19. The cap element would be seen to remain outside of and abut the incision as the device of Figure 19 is being inserted through the incision. With respect to claim 89, see lines 15-35 of column 16. With respect to claims 90 and 91, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 21-36 of column 10 and line 9 of column 15 to line 35 of column 16).

11. Claims 83-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (U.S. Patent No. 5,551,427). Altman discloses a method of treating a patient comprising delivering a delivery device comprising a helical, substantially Z-shaped, body member (46) having at least five deviations from a linear path and that has a shape other than a substantially C-configuration and a cap element (54) at a proximal

end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The body member (12) has a coil shape or zig-zag shape as seen in Figures 7-11. The cap element would be seen to remain outside of and abut the incision as the device of Figure 7 is being inserted through the incision.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 68-91, 93-97, 99-109, 111-127, and 129-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al (U.S. Patent No. 5,466,233) in view of Darougar et al (U.S. Patent No. 5,395,618).

Weiner et al disclose an implantable drug delivery device having a non-linear shaped body member (12) and that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (16) (see Figure 1). The cap element is sized to provide a cross-section larger than the cross-section of the non-linear body member such that the cap element abuts an incision through which the device is inserted to stabilize the device. With respect to claims 69-71, the device body

member comprises at least five deviations from a linear path as seen by the multiple surfaces of the body member. The cap element is seen to be capable of mating against the patient eye outer surface when the body member is inserted into the eye. The cap element mates the body member at a proximal end of the device as seen in Figure 1. The cap element is in contact with the body member. With respect to claim 76, Weiner et al disclose the device comprising a therapeutic agent for delivery to the patient during use of the device (line 33 of column 10 to line 27 of column 11). With respect to claims 77 and 78, Weiner et al disclose the device body comprising a polymer that comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claims 83-86 and 99-102, Weiner et al disclose a method of treating a patient comprising delivering a delivery device comprising a non-linear shaped body member (12) having at least five deviations from a linear path and a cap element (16) at a proximal end, inserting into a patient through an incision the device whereby the body member resides in the patient and the cap element remains outside the incision through which the device is inserted and abuts the incision to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The cap element is seen to remain outside of and abut the incision as seen in Figure 14 where the device of Figure 1 is inserted into a patient eye such that the body member resides in the patient eye. With respect to claims 89 and 105, see line 33 of column 10 to line 27 of column 11. With respect to claims 90, 91, 106, and 107, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claim 108, the cap element

mates against the outer surface of the patient eye. With respect to claim 109, the device is inserted by screwing the device into the eye. With respect to claim 117, the incision comprises a sclerotomy. With respect to claim 118, the device is implanted in a minimally invasive surgical procedure. With respect to claims 119 and 120, the device is implanted at the pars plana and the body member is in contact with intravitreal fluid (lines 29-50 of column 5 and line 24 of column 14 to line 5 of column 16). With respect to claims 121 and 131, the body member is formed of a tube and the tube has a cross-sectional diameter approximately equal to that of an incision through which the device is being inserted (see Figure 14). With respect to claim 130, the cap element is sized to provide a cross-section about twice as large as the cross section of the non-linear body member (see line 10 of column 5 to line 10 of column 6). With respect to claims 122-127 and 132-137, see line 46 of column 8 to line 52 of column 9 and line 65 of column 9 to line 32 of column 10. With respect to claim 116, Weiner et al disclose an implantable ocular drug delivery device having a non-linear shaped body member (12) that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye via the body member and a cap element (16) (see Figure 1). The cap element is sized to prevent the cap element from passing through an incision through which the device is inserted and the cap element is configured to mate against the patient eye outer surface while the body member is inserted to the eye.

Weiner et al disclose the implantable drug delivery device substantially as claimed. Even though Weiner et al disclose a non-linear shaped body member, Weiner et al are silent on the specifics of the body member comprising a coil or zig-zag shape.

Darougar et al disclose an implantable drug delivery device having a non-linear body member which comprises a coil or zig-zag shape as seen in Figures 8 and 12. The body member can also be considered to comprise a helical shape or a substantially Z-shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil or zig-zag shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the cap element of Weiner et al is sized to provide a cross-section larger than the cross-section of the non-linear body member, providing the body member of Weiner et al with a coil or zig-zag shape would result in the cap element of Weiner et al being sized to provide a cross-section larger than the cross-section of the coil or zig-zag shape.

As to claims 79-82 and 129, Weiner et al disclose the drug delivery device substantially as claimed. However, Weiner et al are silent on the specifics of the body member being coil-shaped. Darougar et al disclose an implantable drug delivery device having a coil-shaped body member as seen in Figures 8 and 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a coil shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the cap element of Weiner et al is sized to provide a cross-section larger than the cross-section of the non-linear body member, providing the

body member of Weiner et al with a coil shape would result in the cap element of Weiner et al being sized to provide a cross-section larger than the cross-section of the coil-shaped body member.

As to claims 93-97, Weiner et al disclose the method substantially as claimed. However, Weiner et al are silent on the specifics of the body member being coil-shaped. Darougar et al disclose an implantable drug delivery device having a coil-shaped body member as seen in Figures 8 and 12. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil shape as taught by Darougar et al as Darougar et al disclose that it is well known to provide an implantable device with a coil shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the cap element of Weiner et al is sized to provide a cross-section larger than the cross-section of the non-linear body member, providing the body member of Weiner et al with a coil shape would result in the cap element of Weiner et al being sized to provide a cross-section larger than the cross-section of the coil-shaped body member.

14. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al in view of Johnson (U.S. Patent No. 5,972,027). Rosenman et al disclose the method substantially as claimed. However, Rosenman et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column

2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rosenman et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

15. Claims 92, 98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al in view of Darougar et al as applied to claims 83, 93, and 99 above, and further in view of Johnson. Weiner et al and Darougar et al disclose the method substantially as claimed. However, Weiner et al and Darougar et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiner et al and Darougar et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

Response to Arguments

16. Applicant's arguments with respect to claims 68-91, 111-116, and 129 and the prior art of Rosenman et al and Altman have been considered but are moot in view of the new ground(s) of rejection. As to claims 83-91, Applicant's arguments in lines 3 of

page 19 to line 6 of page 20 are not deemed persuasive. Specifically, there is no recitation in claims 83-91 of the device being inserted into the eye as mentioned in Applicant's arguments. Rosenman et al disclose inserting the device through an incision as claimed. As to claims 83-91, Applicant's arguments in lines 11-20 of page 20 are not deemed persuasive. Specifically, there is no recitation in claims 83-91 of the cap element being sized to provide a cross-section larger than the cross-section of the body member. Altman discloses inserting the device through an incision as claimed.

17. Applicant's arguments in line 7 of page 21 to line 19 of page 22 with respect to claims 68-91, 93-97, 99-109, 111-120, and 129 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's arguments that Darougar et al does not show a coil or zig-zag shaped body member, the body member of Darougar et al is seen to have a coil or zig-zag shape as seen in Figures 8 and 12. Both the screw-type protrusions and the braid design of Darougar et al are in the shape of a coil or a zig-zag. It is not clear what is meant by the coil or zig-zag shapes of Darougar et al not fitting in within applicant's description of a coil or zig-zag shaped body member as the coil or zig-zag shaped body member of Darougar et al has the same structure as applicant's coil or zig-zag shaped body member. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Weiner et al and Darougar et al disclose devices with anchoring structure and methods for drug delivery devices to be inserted into the eye of a patient and it is the coil or zig-zag shape that allows the device of Darougar et al to be securely anchored that is being applied to the device of Weiner et al as both Weiner et al and Darougar et al teach that it is beneficial and highly desirable to securely anchor the drug delivery device in the eye of the patient.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767